## **REMARKS**

Claims 1-20 are pending in the application, claims 18-20 are withdrawn from consideration, and claims 1-16 have been amended. Support for the claim amendments may be found throughout the specification, including the claims as originally filed. No new matter has been added.

Amendment of the originally filed claims or cancellation of any claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

# **Priority Information**

Applicants respectfully request insertion of the priority information into the specification as requested by the Examiner.

### <u>IPER</u>

The IPER was submitted on March 25, 2002 as part of the Transmittal Letter to the U.S. Designated Office for Entry into the National Stage under 35 U.S.C. § 371. A courtesy copy is provided for the Examiner's convenience.

# Sequence Requirements

A Statement to Support Filing and Submission of Sequence Listing in Accordance with 37 CFR §§ 1.821-1.825, a paper copy of sequence listing, and a computer readable form (CRF) of the sequence listing were submitted on March 25, 2002 as part of the Transmittal Letter to the U.S. Designated Office for Entry into the National Stage under 35 U.S.C. § 371. A courtesy copy of the Statement to Support Filing and Submission of Sequence Listing in Accordance with 37 CFR §§ 1.821-1.825 and a paper copy of sequence listing is provided for the Examiner's convenience. Accordingly, Applicants believe that this application meets all sequence requirements under 37 CFR §§ 1.821-1.825.

# Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-17 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Applicants respectfully traverse these rejection.

Applicants respectfully submit that to satisfy the enablement requirement the "specification must contain "sufficient information regarding the subject matter of the claims as to enable on skilled in the art to make and use the claimed invention" M.P.E.P. § 2164.01. In addition, "[t]he test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation" (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988); MPEP §2164). Furthermore, "[a]ll questions of enablement are evaluated against the claimed subject matter" M.P.E.P. § 2164.08.

The Examiner asserts that "[n]o compounds are disclosed which have been found by the presently claimed screening method." Office Action at p. 3. The claims are not directed to compounds, as the Examiner indicates, but are "directed to a high throughput screening methods for biological agents affecting fatty acid biosynthesis."

The Applicants submit that the instant specification provides sufficient guidance to enable one of skill in the art to make and use each element of the claimed screening assay. For example, an acyl carrier moiety, a component of a reaction mixture, may be produced by overexpression in an *E. coli* expression system (see Examples 1 and 3, pg. 48-49) or synthesized as holo-ACP (see Example 5, pg. 49), acetyl-ACP (see Example 6, pg. 49) malonyl-ACP (see Examples 7 and 8, pg. 50), acetoacetyl-ACP (see Example 9, pg. 50), D-3-hydroxybutyryl-ACP (see Example 10, pg. 50-51), crotonoyl-ACP (see Example 11, pg. 51) or butyryl-ACP (see Example 12, pg. 51). Subsequent reactions may be initiated by the addition of FabD enzyme, FabH enzyme, FabG enzyme, FabA or FabZ enzyme, and/or FabI enzyme as described on pages 37-38 and 51-54 of the instant specification. Further, in the presence of a bioactive agent the enzymatic activity of any of the above enzymes can be measured. One of skill in the art is then able to determine if presence of the bioactive agent altered the activity of one of the above enzymatic pathways (see Example 13 for FabD assays (pg. 51), Examples 14 and 15 for FabH

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assays (pg. 52), Examples 16 and 17 for FabG assays (pg.52-53), Example 18 for FabZ assays (pg. 53), and Example 19 for FabI assays (pg. 53-54)).

As the Examiner notes, "[e]ach of the single enzymatic reactions and how to assay them would be expected to be useful in finding inhibitors of that reaction known to be necessary for fatty acid biosynthesis and the same single assay are taught in the art of record for the same function as claimed." Office Action at p. 3. Thus, it is respectfully submitted that one of skill in the art could use the claimed method without undue experimentation. Accordingly, withdrawal of these rejections under §112, first paragraph, is respectfully requested.

## Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

In particular, claim 1(A)(1)(b) "the enzymes", claim 2, line 1 "the high throughput screen", claim 6(1) "the consumption, claim 7, line 2 "the reacting step", and claim 7, last line "the assay" were all cited as lacking antecedent basis. Claims 1, 2, 6, and 7 have been amended as suggested by the examiner. Applicants have also amended Claims 3, 4, 5, and 8-16 based on the Examiner's suggestions. This amendment is believed to obviate the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

### **Title**

The Examiner has indicated that the title of the invention is not descriptive. Applicants respectfully disagree, however, in an effort to expedite prosecution of the application, the title is amended to recite "A High Throughput Screening Method for Biological Agents Affecting Fatty Acid Biosynthesis." Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

#### **Abstract**

An abstract of the disclosure as required by 37 CFR § 1.72(b) listing was submitted on March 25, 2002 as part of the Transmittal Letter to the U.S. Designated Office for Entry into the

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National Stage under 35 U.S.C. § 371. A copy of the Abstract is provided on a separate sheet as requested by the Examiner.

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## **CONCLUSION**

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance. Early and favorable consideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to Deposit Account Number 06-1448, Reference IPT-0062.01.

**Customer Number: 25181** 

Dated: January 7, 2005 Patent Group Foley Hoag LLP

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